UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

February 5, 2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
Kwikkill Disinfectant Deodorizing Spray

DP Barcode: 270420 **Reg. No. Or File Symbol: 59894-O**
Manufacturing-use [ ] OR **End-use Product [X]**

TO: Marshall Swindell/Martha Terry
PM Team No. 33

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2/8/01

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Product Formulation **Active Ingredient(s)**	**% by wt.**
Isopropyl alcohol	41.58%
n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chloride	0.12%
n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethyl benzyl ammonium chloride	0.12%

BACKGROUND:

The registrant is requesting a new registration for this spray product which is used on

non-porous hard surfaces as a disinfectant and deodorizer. The initial product chemistry review was conducted at Oak Ridge National Laboratories. The product chemistry data were submitted in one volume (MRID 452291-01) with an additional volume as a "confidential appendix" which contained only Manufacturers Safety Data Sheets. Also submitted was a handwritten Confidential Statement of Formula and a label which does not appear to be complete.

FINDINGS:

1. The nominal concentration of the dual quaternary ingredient is not listed on the Confidential Statement of Formula. The ingredient is a 50% concentration and should be indicated as 0.24%, or 0.12% for each of the two components.

2. The concentration of the active ingredient isopropyl alcohol is incorrectly calculated. The purity of the ingredient is stated to be 99%, which would provide a nominal concentration of 41.58%, not 42% as listed. "Rounding off" of nominal concentrations are permitted only after two places beyond the decimal.

3. The label ingredient claims statement lists the concentration of isopropyl alcohol as 42.2%. It is not evident from the data the source of this figure. It should be listed as 41.58% so that the Confidential Statement of Formula and the label ingredient claims statement are in agreement, conforming to PR Notice 91-2.

4. The active ingredient isopropyl alcohol is an unregistered ingredient. The supplier should provide a certificate of analysis to the Agency to verify its use. A copy of that certificate was not in the data package, although there was an MSDS from the supplier of the ingredient included in the submission.

5. The certified upper and lower limits of most of the ingredients are within range of the Agency standards set forth in 40 CFR, Part 158.175. The limits for [redacted] however, are wider than the Agency guidelines, and no request for an exception was requested. There is no support data or explanation for those out-of-range limits in the documentation.

6. The 830 Series Product Chemistry Guidelines, Part A are complete with the exception of those discrepancies listed above. It would have been helpful if the temperature and the type of vessel used at the time of blending had been provided in the description of the manufacturing process.

7. All of the physical and chemical characteristics (Series 830, Part B) are complete except for 830.6303 (odor), 830-6314 (oxidization/reduction) and 830.6315 (explodability). These parameters must be addressed by providing an explanation of the lack of applicability of the value, request for a waiver, or the value of the characteristic. No details were provided about the corrosion characteristics (830.6320) of the product except for the use of "moderate" as a

descripter. It is expected that this will be addressed at the completion of the one-year storage stability/corrosion characteristics testing period.

8. The label is incomplete. It does not contain any precautionary statements, nor is there any storage/disposal statement. There is no restrictive statement about the use of the product around food. All of these statements are required to appear on the label.

9. There is inconsistency among the CAS numbers used for the quaternary ammonium active ingredient on the Confidential Statement of Formula and those in the Agency database. At a later date, when the inconsistencies are resolved, the registrant may be asked to correct the numbers. At the present time, the CAS numbers provided by the suppliers for their ingredients should be used.

10. There is a statement in the document (MRID 451291-01, page 4) about iron being an impurity, but since this is a blended product, no such impurity should be present. There is no further indication about the origin of the impurity or any explanation for its presence in the formulation.

11. There is no explanation about the methods used to obtain the values of the Part B data except for pH.

RECOMMENDATIONS:

1 The registrant must submit a revised Confidential Statement of Formula (preferably typed for readability and clarity) which corrects the nominal concentration of the dual quaternary active ingredient so that it is in agreement with the label ingredient claims statement. The current Confidential Statement of Formula, dated May 18, 2000 is unacceptable.

2. The upper and lower certified limits of [redacted] must be adjusted to meet Agency standards [redacted] for the upper limit and [redacted] for the lower). If the registrant wants to ask for an exception to the standards and use wider limits, the request must be accompanied by a justification for the wider limits based on data which supports the wider limits (40 CFR, Part 158.175 (c)(4)).

3. The Series 830 Guidelines for Part B which are missing (830. 6314, .6315. and .6320) must be addressed. See attached below for summary of data submitted with this package.

4. A revised label which includes all the required statements must be sent to the Agency for review and approval

5. It is expected that a final one-year storage stability/corrosion characteristics study will be submitted to the Agency when the study is completed.

6. Methods used to obtain values for the Part B Guidelines should be provided.

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
  - Are all TGAIs used registered? Yes [ ] No [X]
- Integrated formulation system [ ]
- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [ ] No [X] NA[ ]

4c. Physical state of product: Liquid

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Part B
Yes [ ] No [X]

4h. NCs and CLs are acceptable: Yes [ ] No [X] Not acceptable [ ]

4i. Active ingredient (s)	NC	LCL	UCL
A. Isopropanol	41.58%	40.33%	42.83
B. n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chloride	0.12%	0 .0108%	0.132%
C. n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethyl benzyl ammonium chloride	0.12%	0.108%	0.132%

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- All impurities of $\geq$ 0.1% in the product have been identified?]
  Yes [ ] No [ ] Not applicable [X]

6. Methods used to obtain values for the Part B Guidelines should be provided.

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
  - Are all TGAIs used registered? Yes [ ] No [X]
- Integrated formulation system [ ]
- if "ME-TOO", specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [ ] No [X] NA[ ]

4c. Physical state of product: Liquid

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Part B
Yes [ ] No [X]

4h. NCs and CLs are acceptable: Yes [ ] No [X] Not acceptable [ ]

4i. Active ingredient (s)	NC	LCL	UCL
A. Isopropanol	41.58%	40.33%	42.83
B. n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chloride	0.12%	0 .0108%	0.132%
C. n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethyl benzyl ammonium chloride	0.12%	0.108%	0.132%

4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- All impurities of $\geq$ 0.1% in the product have been identified?]
  Yes [ ] No [ ] Not applicable [X]

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC] is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [ ] No [X]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- Sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [ ] No [ ] Not applicable [X]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [ ] No [X] Not on label

5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes [X] No [ ]

7. **PRODUCT CHEMISTRY (830 Series, Part B)**

Guideline	Acceptance of Information	MRID No.
830.1550[1] Product Identity	A	451291-01
830.1600 Description of Materials	N Isopropanol	451291-01
830.1620 Production Method[2]	A	451291-01

Guideline	Acceptance of Information	MRID No.
830.1650 Formulation process[3]	A	451291-01
830.1670 Formation of impurities[4]	NA Iron	451291-01
830.1700 Preliminary Analysis[5]	A	451291-01
830.1750 Certified Limits[6]	N	451291-01
830.1800 Analytical Method[7]	A Cl titration	451291-01
830.1900 Submittal of Samples	N Was sample sent to EPA Lab?	

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information

[2]For MP/EP products produced by an integrated formulation system.

[3]For products from a TGAI or MP.

[4]May be waived unless actual/possible impurities are of toxicological concern.

[5]Five batch analysis required for products produced by an integrated formulation system.

[6]If different from standard Cls recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

6b. Physical/Chemical Properties*	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	Light yellow	451291-01
830.6303 Physical state	A	Liquid	45129101
830.6303 Odor	G		
830.7200 Melting point	NA	Not a solid	451291-01

830.7220 Density/Relative density/bulk density	A	8.05 lbs./gal	451291-01
830.7000 pH[1]	A	5.5	451291-01
830.6314 Oxidation/Reduction	G	No explanation	451291-01
830.6315 Flammability	G	Not addressed	
830.6317 Storage stability	A	Pending	451291-1
830.7100 Viscosity	A	3-5 cPs	451291-01
830.6319 Miscibility[2]	A	100%	451291-01
830.6320 Corrosion Character.	U	Pending	451291-01
830.6321 Dielectric breakdown	A	Not applicable	451291-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25 ^{0}C.

[1] If product is dispersible with water

[2] If product is an emusifiable liquid